

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

V.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9087

Bartle, J.

June 6, 2013

Kelly M. Woodman ("Ms. Woodman" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Jeffrey A. Wolcott, Ms. Woodman's brother, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert N. Notske, M.D., F.A.C.C., F.A.C.P. Dr. Notske is no stranger to this litigation. According to the Trust, he has attested to at least 45 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 1, 2002, Dr. Notske attested in Part II of Ms. Woodman's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$567,341.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Khusrow Niazi, M.D., F.A.C.C., stated that claimant had moderate mitral regurgitation, which he measured at 29%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for Dr. Notske's finding that claimant suffered from moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Parmar explained,

4. Dr. Notske also attested that the claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV. B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

The [mitral regurgitation] is mild by Singh criteria. The [echocardiogram] technician has over-estimated the [RJA] by inclusion of low velocity flow. The LAA has been under-estimated. These mis-assessments has [sic] erroneously given an elevated [RJA]/LAA ratio. My calculation shows mild [mitral regurgitation] by Singh criteria (by my assessment the [RJA]/LAA ratio is 12%).

Based on Dr. Parmar's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Woodman's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted declarations of Dr. Notske and William S. Murphy, M.D., F.A.C.C., F.C.C.P. In his declaration, Dr. Notske stated:

Both the Trust screening cardiologist and the attesting cardiologist found that there was moderate mitral regurgitation based upon the Singh criteria. The auditing cardiologist cites no violation of either Feigenbaum or Weyman in how the echocardiogram was performed or interpreted by the Trust screening cardiologist or the attesting cardiologist....

....

The auditing cardiologist states "[t]he [echocardiogram] technician has over-estimated the [RJA] by inclusion of low

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Woodman's claim.

velocity flow. The LAA has been under-estimated." The lower portion of the mitral regurgitation jet, which was measured, contains the scintillation phenomenon associated with higher velocity flow. Also, "[w]ith transthoracic echocardiography [as distinguished from transesophageal echocardiograms], however, one should take the entire mitral regurgitant jet, including the surrounding, lower flow spray." Feigenbaum, at 253 [emphasis added]. In other words, the Feigenbaum text requires a more expansive measurement of the regurgitant flow area than the measurement of the auditing cardiologist.

The auditing cardiologist also asserts that the "LAA has been under-estimated," but ... the Trust's screening cardiologist's measurements, at least based upon the apical four chamber view and the parasternal long axis view, are larger than those of the auditing cardiologist.

In his declaration, Dr. Murphy stated that he concurred with Dr. Niazi's assessment that the echocardiogram demonstrated that claimant had "moderate mitral regurgitation equal to or exceeding 20% RJA/LAA."

The Trust then issued a final post-audit determination, again denying Ms. Woodman's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the Court for issuance of an Order to Show Cause why Ms. Woodman's claim should be paid. On January 19, 2006, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 5953 (Jan. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant served a response upon the Special Master. The Trust submitted a reply on May 5, 2006, and claimant submitted a sur-reply on June 1, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had an opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the Court. The Show Cause Record and Technical Advisor Report are now before the Court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Woodman argues that Dr. Notske's finding of moderate mitral regurgitation has a reasonable medical basis because (1) three preeminent cardiologists have independently found moderate mitral regurgitation; (2) her echocardiogram was performed as part of the Trust's Screening Program⁸; (3) the reasons given by the auditing cardiologist for his finding of mild mitral regurgitation are flawed; and (4) the auditing cardiologist failed to articulate how Dr. Niazi and Dr. Notske did not follow the procedures set out by Feigenbaum and Weyman. Claimant also contends that the auditing cardiologist improperly excluded "lower flow spray" from his regurgitant jet area measurement because the Feigenbaum text directs physicians to include lower flow spray and because the Weyman text directs physicians to identify "the maximal jet area in any frame." In addition, claimant says that the jet identified by Dr. Notske was not backflow because it consisted of a color mosaic. Claimant also relies on a supplemental declaration of Dr. Notske, in which he states, "The regurgitant jet that I observed was a mosaic of

8. See Settlement Agreement § IV.A.1.a (Screening Program established under the Settlement Agreement).

colors reflecting a high velocity jet, not backflow." Finally, claimant argues the auditing cardiologist's criticism that the left atrial area was underestimated is incorrect because the auditing cardiologist's measurements were, in fact, smaller than those taken by Dr. Niazi and relied upon by Dr. Notske.

In response, the Trust argues that the auditing cardiologist properly applied the reasonable medical basis standard. In addition, the Trust asserts that there is no reasonable medical basis for Dr. Notske's representation of moderate mitral regurgitation because the jet upon which Dr. Notske relied is backflow, as it appears only in very early systole and is of an extremely short duration. Finally, the Trust contends that the auditing cardiologist properly conducted the audit and that neither the Settlement Agreement nor the Audit Rules requires an auditing cardiologist to demonstrate how an attesting physician failed to consider Feigenbaum and Weyman.

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Woodman had moderate mitral regurgitation. Dr. Burke stated:

My impression of the August, 1, 2002 echocardiogram, by visual inspection, is that the mitral regurgitation is trace. There were multiple beats in each view in which I could detect no mitral regurgitation. I agree with the conclusion of Rohit Parmar, M.D., that some of the color flow seen in the left atrium represents backflow and not mitral regurgitation.

Dr. Burke independently measured RJA/LAA ranges of 1% to 5%, 2% to 5%, and 1% to 4% in the parasternal long axis, apical four chamber, and apical three chamber views, respectively.

In response to the Technical Advisor Report, claimant argues that all three of her experts concluded she had moderate mitral regurgitation and that all three followed "the most common approach" by "including the lower flow spray." According to claimant, the Technical Advisor did not examine whether her experts used the most common approach, did not rebut Dr. Notske's declaration, did not differentiate between backflow and mitral regurgitation, and did not disclose the basis for his protocol. Rather, claimant asserts, the Technical Advisor "simply did his own measurements."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. We disagree with claimant that "lower flow spray" is considered mitral regurgitation. We have consistently held that conduct "beyond the bounds of medical reason" can include characterizing low velocity flow as mitral regurgitation and overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 11-13, 15, 22, 26 (Nov. 14, 2002). We have further found that "[o]n a color flow Doppler echocardiogram, mitral regurgitation will thus display as a high velocity, mosaic blue/green teardrop shaped jet that borders the mitral valve leaflets and expands into the left atrium throughout at least a portion of systole." Id. at 10-11 (footnote omitted). There is nothing to indicate that including

low velocity flow as mitral regurgitation is permissible under the Settlement Agreement.

Significantly, claimant does not contest that her physicians included low velocity flow as mitral regurgitation in determining that she had moderate mitral regurgitation. In addition, Dr. Parmar reviewed claimant's echocardiogram and observed that "the [echocardiogram] technician has over-estimated the [RJA] by inclusion of low velocity flow."⁹ Dr. Burke also reviewed claimant's echocardiogram and determined the measurement of the left atrium represents backflow and not mitral regurgitation."¹⁰ Moreover, Dr. Parmar determined that "the LAA has been under-estimated."¹¹ Such unacceptable practices cannot

9. Thus, contrary to claimant's contention, Dr. Parmar adequately articulated why there is no reasonable medical basis for Dr. Notske's conclusion that Ms. Woodman had moderate mitral regurgitation.

10. For this reason as well, we reject claimant's argument that Dr. Burke simply substituted his own measurements. We also reject claimant's argument that Dr. Burke did not set forth the methodology he used in reaching his conclusion. To the contrary, Dr. Burke stated, "My review of the Claimant's record was performed in accordance with the standards set forth in the Green Form and in the Nationwide Class Action Settlement Agreement with American Home Products Corporation."

11. Although claimant contends that Dr. Parmar's opinion is undermined because he measured Ms. Woodman's left atrial dimension as smaller than Dr. Notske measured it, Dr. Notske concedes that "the left atrial systolic dimension (which is used to determine whether there is enlargement of the left atrium) is not identical with the left atrial area (which is used to determine the severity of mitral regurgitation)." Therefore, we find no inconsistency in Dr. Parmar's conclusions.

provide a reasonable medical basis for the resulting diagnosis and Green Form representation of moderate mitral regurgitation.

We also disagree with claimant's argument that one measurement of a single jet of extremely short duration taken in early systole may form the basis for Matrix Benefits. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the finding of the requisite level of mitral regurgitation is representative of the level of regurgitation throughout the echocardiogram."¹² PTO No. 6997 at 11 (Feb. 26, 2007); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." See PTO No. 6997 at 11.

Finally, claimant's argument is misplaced to the extent she argues that she is entitled to Matrix Benefits because an echocardiogram conducted in the Screening Program for Fund A Benefits under the Settlement Agreement demonstrates moderate mitral regurgitation. See Settlement Agreement § IV.A. The

12. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive based on an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit for all claims for Matrix Benefits. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate

entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Woodman's claim for Matrix Benefits and the related derivative claim submitted by her brother.